UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,)
)
Plaintiff,)
)
v.)
)
MICHAEL MIMLITZ,)
)
Defendant.)

4:16CR00020 CDP

INFORMATION

The United States Attorney charges that:

The Defendant

1. At all times relevant to this Indictment, defendant Michael "Ted" Mimlitz was a resident of St. Louis County, Missouri. Mimlitz was a licensed medical doctor, and was employed at a medical clinic that maintained an office in St. Louis County, Missouri, all within the Eastern Division of the Eastern District of Missouri.

Background

Human Growth Hormone

2. Human Growth Hormone (commonly known as HGH and sometimes sold in the United States as Saizen®) means Somatrem, Somatropin, or an analogue of either of these drugs. 21 U.S.C. § 333(e)(4). This drug is therapeutically equivalent to HGH created by the pituitary gland of a healthy human being. HGH has been approved by the U.S. Food and Drug Administration ("FDA") for several narrow medical uses, such as short stature in children with chronic renal insufficiency disease, Turner or Prader-Willi syndromes, or adults with wasting diseases associated with AIDS. The FDA has not approved HGH for any body-building, anti-

aging, or weight loss treatment. HGH has not been shown to be safe and effective for the enhancement of athletic performance. The Food, Drug, and Cosmetic Act prohibits the knowing distribution of HGH for any use in humans other than for the treatment of disease or other recognized medical condition where such use has been authorized by the FDA and pursuant to the order of a physician. 21 U.S.C. § 333(e).

3. Defendant's medical clinic, according to marketing materials prepared by the clinic, specialized in treating men who were experiencing a lack of energy, decreases in strength and endurance, and decreased athletic ability. Defendant's clinic did not create marketing materials offering treatment services for children with chronic renal insufficiency disease, patients with Turner or Prader-Willi syndromes, or treatment for adults with wasting diseases associated with AIDS..

4. During the Spring of 2014, defendant contacted a HGH distributor who had a bank account in the United States. On or about March 30, 2014, Mimlitz sent an e-mail to an associate of this HGH distributor, seeking HGH for use at defendant's clinic for male patients who wanted increased energy, strength, endurance, and athletic ability. The associate advised Mimlitz that because of "heat" from "USA and FDA for processing growth hormone," credit cards could not be used for purchasing HGH. Instead, the associate told Mimlitz to fund HGH transactions by sending direct deposits to the HGH distributor's bank account.

5. From on or about March 30, 2014 through on or about June 17, 2015, Mimlitz and the HGH distributor engaged in numerous HGH transactions for approximately 40 of defendant's local HGH patients, with Mimlitz sending direct deposits to the HGH distributor's bank account to fund HGH purchases for assorted clinic patients.

6. After the HGH arrived in St. Louis County, Missouri, Mimlitz distributed and dispensed the HGH to local patients in the Eastern District of Missouri who wanted to increase their energy, strength, endurance, and athletic ability. Mimlitz had some of the HGH sent to patients' addresses, and some of the HGH sent directly to his medical office.

7. The HGH that defendant ordered for his patients or received at this clinic was different than the U.S. FDA-approved versions of HGH that are lawfully sold in the U.S. For example, the HGH that defendant distributed had different labeling (e.g. dosage and use instructions in Spanish not English), different drug trade names (e.g. "Yelit" instead of the FDA-approved drug Serostim®), and different drug formats from the FDA-approved versions of HGH (e.g. glass ampules instead of vials or single use syringes). The HGH also came from drug manufacturers (e.g. Dong-A Pharmaceutical) that had not registered as drug establishments with FDA. As such, the HGH was misbranded.

8. After receiving some of the HGH at his medical practice, Mimlitz -- through his office staff -- delivered some of the HGH to his patients for pay. Mimlitz charged his patients higher prices for the HGH than what it cost Mimlitz to acquire the HGH from the HGH distributor. Some of defendant's HGH patients complained of health problems or a lack of improvement to Mimlitz from the HGH, and stopped using HGH.

COUNT ONE

9. Paragraphs 1 through 8 are incorporated by reference, as if fully set forth herein.

10. On or about May 5, 2015, in St. Louis County, Missouri, Michael Mimlitz, defendant herein, with the intent to defraud or mislead, introduced for delivery into interstate commerce, from Mexico to Missouri, a three monthly supply of Human Growth Hormone

labeled as "Yelit," for patient B.S., that was misbranded. Specifically, each quantity of the drug was misbranded in the following ways:

(a) the drug's labeling did not bear adequate directions for use, as the dosage and use instructions were in the Spanish language;

(b) the drug came from an unregistered foreign drug establishment located in South Korea and this unregistered drug establishment did not annually list this drug as something which it was manufacturing for commercial distribution in the United States. All in violation of 21 U.S.C. §§ 331(c), 333(a)(2), 352(f)(1), 352(o), and 360(j) and 18 U.S.C. § 2.

UNITED STATES OF AMERICA)
EASTERN DIVISION)
EASTERN DISTRICT OF MISSOURI)

I, Andrew J. Lay, Assistant United States Attorney for the Eastern District of Missouri, being duly sworn, do say that the foregoing information is true as I verily believe.

Richard G. Callahan
United States Attorney

Andrew J. Lay #39937MO
Assistant United States Attorney

Subscribed and sworn to before me this 15 day of December, 2015.

Gregory Linhares
CLERK, U.S. DISTRICT COURT

By: Elizabeth Kirkland
DEPUTY CLERK